K103396

i-SENS, Inc.
465-6 Wolgye-dong, Nowon-gu, Seoul 139-845, Korea Tel. 82-2-916-6191

SEP 2 7 2011

510(k) Summary

(As required by 21 CFR 807.87)

Introduction: According to the requirements of 21 CFR.807.92, the following information provides data needed to understand the basis for determining substantial equivalence.

510(k) Number is: **k103396**

Type of 510(k): **Special 510(k)**

Submitted By:
i-SENS, Inc.
465-6, Wolgye-dong, Nowon-gu, Seoul 139-845, Korea
Tel.) +82-2-916-6191
Fax) +82-2-942-2514
www.i-sens.com

Contact Person:
Martin Saperstein
GOODMAN & SAPERSTEIN
Tel.) 1-516-227-2100
Fax) 1-516-227-2108

Device Name:
Trade name: **COOL Blood Glucose Monitoring System**
Common Name: Glucose Test System

Device Classification:
* COOL Blood Glucose Meter and Test Strips

Product Code	Classification	Regulation Section	Panel
CGA - glucose oxidase, glucose	Class II	21 CFR 862.1345	75, Chemistry
NBW - system, test, blood glucose, over the counter	Class II	21 CFR 862.1345	75, Chemistry

* COOL Control Solution

Product Code	Classification	Regulation Section	Panel
JJX - Quality control material	Class I	21 CFR 862.1660	75, Chemistry

Type of Test: Quantitative, Amperometric method
Enzyme: Glucose oxidase *(Aspergillus sp.)*

System Description: The COOL Blood Glucose Monitoring System (BGMS) measures the glucose in whole blood sample by a small electrical current generated in the test strips and sent to the meter for measurement. The system consists of the following devices: COOL Meter (Model GM505MA), COOL Test Strips, COOL Control Solutions for two different glucose concentration ranges (called "Normal" and "Middle" ranges, sold separately), Lancing Device, Lancets, User manual, Quick reference guide and Logbook.

Intended Use: The COOL Blood Glucose Meter is intended for use with the COOL Blood Glucose Test Strips for the quantitative measurement of glucose in capillary whole blood from the fingertip and the alternate sites such as forearm, palm, thigh and calf. The alternate site testing should be used only during steady-state blood glucose conditions. The COOL Control Solutions are for use with the COOL Meter and COOL Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.
The COOL Blood Glucose Monitoring System is intended for self testing outside the body by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis of or screening for diabetes.

Predicate Device: Device name: **CareSens N Blood Glucose Monitoring System**
510(k) Number: k083468

Comparison with Predicate Device:

The modified COOL BGMS has the following similarities to the predicate device:

1) same intended use,
2) same operating principle,
3) same fundamental scientific technology,
4) same product specifications,
5) same operating ranges,
6) manufactured by the same process.

The modifications from the predicate device are as follows:

1) Meter **outer casing design** change,
2) **Electric connector pattern** of test strip change.

Technological Characteristics:

The COOL BGMS has the same fundamental scientific technology as the predicate CareSens N BGMS.

Assessment of Performance:

The all specifications of the COOL BGMS are identical the CareSens N BGMS. The differences are **only** the physical design of meter and electric connector pattern of the test strip. Accordingly, the performance evaluations such as altitude, hematocrit studies were not conducted. But, to verify whether the modified electric connector of COOL test strip operates properly with the COOL meter, the repeatability and linearity tests were conducted. The test results confirmed that the modified electric connector of the strip operated properly with the meter. Thus, COOL BGMS demonstrated satisfactory performance and is suitable for its intended use.

<table>
<tr><th>Report No. & Title</th><th>Pre-determined Acceptance Criteria</th><th>Met pre-determined acceptance criteria?</th></tr>
<tr><td>PE-01 Repeatability Test</td><td>
<table>
<tr><th>Interval</th><th colspan="2">Mean concentration (mg/dL)</th><th>Acceptance criteria</th></tr>
<tr><td>1</td><td colspan="2">30 to 50</td><td>SD<7.7 mg/dL</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">51 to 110</td><td><100</td><td>SD<7.7 mg/dL</td></tr>
<tr><td>≥100</td><td>CV<7.5%</td></tr>
<tr><td>3</td><td colspan="2">111 to 150</td><td>CV<7.5%</td></tr>
<tr><td>4</td><td colspan="2">151 to 250</td><td>CV<7.5%</td></tr>
<tr><td>5</td><td colspan="2">251 to 400</td><td>CV<7.5%</td></tr>
</table>
</td><td>Yes</td></tr>
<tr><td>PE-03 Linearity Study</td><td>
<table>
<tr><th>Item</th><th>Acceptance criteria</th></tr>
<tr><td>Correlation coefficient (r)</td><td>≥ 0.97</td></tr>
<tr><td rowspan="2">Bias: Linear equation (y = Ax + B)</td><td>0.95 < A < 1.05</td></tr>
<tr><td>-5 < B < 5</td></tr>
</table>
</td><td>Yes</td></tr>
</table>

Conclusion: **The modifications of COOL BGMS do not affect the safety and effectiveness of the device and the intended use. Therefore, based on the information provided in this submission, the COOL BGMS is substantially equivalent to the predicate CareSens N BGMS.**

MEMO TO FILE

DATE: October 5, 2011
TO: File
RE: k103396, Product Code Correction for iSens COOL Blood Glucose Monitoring System
FROM: Christine King, Scientific Reviewer, CDRH/OIVD/DCTD

A correction letter needs to be sent to the sponsor and the CTS product codes need to be updated. The product code LFR (glucose dehydrogenase) needs to be replaced with CGA (glucose oxidase). The other product codes, NBW and JJX remain the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

i-Sens, Inc.
c/o Goodman and Saperstein
100 Garden City Plaza, Suite 412B
Garden City, NY 11530

Re: k103396
Trade/Device Name: COOL Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: 862.1345, Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: 13 September 2011
Received: 14 September 2011

OCT - 5 2011

Dear Mr. Saperstein:

This letter corrects our substantially equivalent letter of September 27, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k103396

Device Name: COOL Blood Glucose Monitoring System

Indications for Use:

The COOL Blood Glucose Monitoring System consists of a measuring meter, test strips and control solutions. The COOL Blood Glucose Meter is intended for use with the COOL Blood Glucose Test Strips for the quantitative measurement of glucose in capillary whole blood from the fingertip and the alternate sites such as forearm, palm, thigh and calf. The alternate site testing should be used only during steady-state blood glucose conditions. The COOL Control Solutions are for use with the COOL Meter and COOL Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The COOL Blood Glucose Monitoring System is intended for self testing outside the body by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis of or screening for diabetes.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103396